**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

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| QUINTESSA HUEY, individually and on behalf of all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>ANAVEX LIFE SCIENCES CORPORATION and CHRISTOPHER U. MISSLING,<br><br>Defendants. | Case No. 1:24-cv-01910-CM |

**DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE AMENDED COMPLAINT**

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The Amended Complaint fails for the simple reason that Plaintiff has not adequately pled her claims. Far from seeking a "trial on the papers," Defendants' motion only seeks to hold Plaintiff to her burden. A plaintiff in a securities fraud action is required to plead *facts* with *particularity* that set out the alleged fraud, which includes the reasons *why* statements are purportedly misleading, and that Defendants acted with scienter, i.e., deliberate, illegal behavior or an extreme departure from the standards of ordinary care. The Opposition (which does not address or respond to a single case cited by Defendants) confirms that all Plaintiff offers here are conclusory statements, assumptions, and innuendo.[1]

## I. Plaintiff Fails to Meet Her Burden to Allege with Particularity Any False or Misleading Statement or Omission of Material Fact

### A. The Allegations Do Not Establish an FDA Endpoint "Requirement"

The Opposition reinforces a fundamental, fatal weakness in the Amended Complaint: Plaintiff does not understand her burden to plead the existence of the supposed FDA "requirement" that all Rett Syndrome studies need to use the same endpoints, which is the central premise of her fraud claims. A plaintiff cannot merely assert that a regulatory requirement exists and demand that the Court deem such a conclusory allegation true at the pleading stage. She must "explain with particularity '*why* the statements were fraudulent,'" which here includes establishing that such an FDA requirement exists and alleging the basis for that assertion. Ark. Pub. Emps. Ret. Sys. v. Bristol-Myers Squibb Co., 28 F.4th 343, 353 (2d Cir. 2022); see Mem. 8-9 (citing cases); see also Garber v. Legg Mason, Inc., 537 F. Supp. 2d 597, 616 (S.D.N.Y. 2008) ("[P]laintiffs are required to plead fraud with particularity and must cite the sources of data that indicate that the basis of the alleged omission existed."). Plaintiff manifestly has failed to do so.

[1] This Reply Memorandum of Law uses the same defined terms as Defendants' Memorandum of Law in Support of their Motion to Dismiss the Amended Complaint ("Memorandum" or "Mem.").

Plaintiff bases this "requirement" assertion solely on her non-particularized allegation that, at a meeting in which neither she nor anyone whom she alleges she has spoken with was present, unnamed persons at the FDA provided "encouragement" to unnamed persons at a separate company (Neuren), which led it to "agree[] to study" CGI-I as co-primary endpoint with RSBQ in its separate study. AC ¶ 36; see Mem. 8-9. The apparent source document for this unsupported allegation confirms that the FDA only "encourage[d]" and "recommended" Neuren to use CGI-I as an anchoring function to RSBQ. Mem. 9 n.8; Ex. 16 at 26, 50. Plaintiff does not assert that any such "requirement" is found in any FDA regulation, policy statement, guidance document, or any other material—the only reference to it is in her own Amended Complaint.

This is not a matter of "semantic[s]," as Plaintiff insists. Opp. 14. When the only reason that the Defendants' statements were allegedly false is a supposed government requirement not found anywhere besides the Amended Complaint itself, Plaintiff must sufficiently plead the existence of that requirement through particularized facts that set out the basis for the allegation. Mem. 8-9. She has not done so here, and the Opposition does not refute any of the authority cited by Defendants on this point. A court only must credit plausible inferences supported by well-pled, particularized facts—it need not accept Plaintiff's conclusory assertion that an FDA requirement exists. Cf. Fort Worth Emps. Ret. Fund v. Biovail Corp., 615 F. Supp. 2d 218, 227-28 (S.D.N.Y. 2009) (rejecting near-identical allegations trying to invent an FDA "requirement" from a "recommendation" conveyed to third parties); Gillis v. QRX Pharma Ltd., 197 F. Supp. 3d 557, 584 (S.D.N.Y. 2016) (holding that plaintiff failed to "plead any specific facts that support an inference that the FDA had adopted, much less alerted [defendant] to," a supposed requirement).

Plaintiff's cases are easily distinguishable, as the operative pleadings in those cases provided more than their own say-so as to the existence of the alleged government requirements.

See Christine Asia Co. v. Ma, 718 F. App'x 20, 23 (2d Cir. 2017) (allegations concerning statements made during key government meeting supported by citation to a government report summarizing that meeting and identification of specific senior executives present);[2] In re Y-mAbs Therapeutics, Inc. Sec. Litig., No. 23-cv-431, 2024 WL 451691, *2-4 (S.D.N.Y. Feb. 5, 2024) (allegations supported by specific FDA documents);[3] In re Didi Global Inc. Sec. Litig., No. 21-cv-5807, 2024 WL 1119483, *6-7 (S.D.N.Y. Mar. 14, 2024) (alleging a Chinese agency that "often works coercively" urged and pressured the defendant in a way reasonable to infer as "tantamount to a directive," citing "numerous, detailed, and consistent news reports from reputable publications reporting" the government statements); Noto v. 22nd Century Grp., Inc., 35 F.4th 95 (2d Cr. 2022) (alleged SEC investigation supported by confidential witness and FOIA request denial).

**B. Statements about FDA Approval Are Inactionable**

Although Plaintiff disclaims that she seeks recovery for statements making promises about FDA approvals, Opp. 17-18, that is essentially what she is doing when she asserts that every statement Defendants made about RSBQ AUC necessarily "implied" or gave the "impression" that the FDA would approve a drug application that was based on studies using such an endpoint. E.g., AC ¶¶ 79, 82, 98. Such claims are inactionable and do not amount to securities fraud. See Mem. 13-14; Biovail, 615 F. Supp. 2d at 231-33.

**C. The Opposition Doubles Down on Demonstrably False Accusations**

Rather than respond to Defendants' arguments, the Opposition merely repeats several of the Amended Complaint's unsupported conclusions and unfounded characterizations of documents properly before the Court. First, the Opposition continues to press the conclusory

[2] See also Compl. at ¶¶ 7, 15, In re Alibaba Grp. Holding Ltd. Sec. Litig., No. 15-md-2631 (2015).

[3] See also Am. Compl. at 20 n.4, In re Y-mAbs Therap., Inc. Sec. Litig., No. 23-cv-431 (2023).

assertion that any time Dr. Missling used the word "guidance," he must have been referring to Plaintiff's "requirement" to only use certain endpoints. Opp. 14-15. Plaintiff entirely ignores that, as explained in the Memorandum, the transcripts are clear that Dr. Missling was referring to an FDA guidance document that he specifically cited orally and on slides during an earnings call. Mem. 12. Next, the Opposition continues to falsely ascribe negative connotations to an exchange between Dr. Missling and an analyst, describing as "contentious" a back-and-forth in which it is clear (see Mem. 12 & n.11) that there was cross-talk during the conference call and Dr. Missling was repeating himself to make sure that the analyst heard and understood the answer. Opp. 15-16. The Opposition makes no attempt to respond to Defendants.

Plaintiff also baselessly concludes that, because Anavex announced partway through the Class Period that it would not be using RSBQ AUC after further FDA conversations, this must be a lie and instead supports that Anavex was finally admitting that the FDA years earlier told Anavex that it could not use RSBQ AUC. Opp. 15-16. Again, such conclusory statements are not entitled to any weight on a motion to dismiss. See Mem. 11 (citing cases).

Finally, the Opposition does not make any attempt to respond about Plaintiff's inaccurate and misleading quote regarding the February 1, 2022, call involving "the preference of the FDA," Mem. 11, or the fact that the Amended Complaint is internally inconsistent when discussing the supposed endpoint "requirement." Mem. 10.

**D. Plaintiff Does Not Dispute that the Excellence Endpoints Were Clearly Disclosed During the Class Period**

The Opposition acknowledges that Anavex disclosed during the Class Period that Excellence would not use RSBQ AUC and that it would instead use the co-primary endpoints of RSBQ and CGI-I. Opp. 16. This means that Plaintiff's case falls apart at least as of the date of the disclosure (February 7, 2023). Mem. 15. Plaintiff nevertheless argues that the endpoints were

not clear, citing statements made *before* that date. Plaintiff misses the point. Although Anavex had earlier planned to use RSBQ AUC, on February 7, 2023, it announced that was no longer the plan.

Plaintiff also incorrectly invokes the truth-on-the-market defense (Opp. 17), which Defendants have not raised and which relates to the materiality element. See, e.g., Ganino v. Citizens Utils. Co., 228 F.3d 154, 166-68 (2d Cir. 2000). Defendants do not argue that disclosure of some additional piece of information altered the "total mix" so as to make earlier misstatements immaterial as a matter of law. The Memorandum asserts that, because Anavex disclosed the actual Excellence endpoints during the Class Period, claims premised on misrepresented endpoints after that date fail for lack of misrepresentation and loss causation. Mem. 15-16. Regardless, courts will dismiss based on a truth-on-the-market defense when it is clear the allegedly omitted information was disclosed. See In re Pfizer, Inc. Sec. Litig., 538 F. Supp. 2d 621, 632 & n.61 (S.D.N.Y. 2008) (noting that "'rarely appropriate' is not the same as 'never appropriate'").

**II. Plaintiff's Failure to Plead Scienter Is Fatal to Her Claims**

In arguing that scienter is pled if a plaintiff alleges that defendants had knowledge of facts contradicting public statements (Opp. 19), Plaintiff ignores the key aspect of her burden under the PSLRA: she must plead *facts with particularity* that establish the Defendants had such knowledge. She cannot simply assert the conclusion.

The cases she cites do not provide otherwise and are easily distinguishable, as those courts found particularized factual allegations establishing knowledge. See Karimi v. Deutsche Bank AG, 607 F. Supp. 3d 381, 397-98 (S.D.N.Y. 2022) (complaint identified "several reports of government investigations and settlements with regulators that provided red flags," as well as internal audit reports and statements by confidential witnesses whose company positions supported they would have had knowledge); Heller v. Goldin Restructuring Fund, L.P., 590 F. Supp. 2d 603, 610 n.8 (S.D.N.Y. 2008) (finding without analysis that scienter was pled with adequate

particularity); In re Scholastic Corp. Sec. Litig., 252 F.3d 63, 76 (2d Cir. 2001) (complaint contained "detailed allegations as to what defendants knew on a daily, weekly and monthly basis").

Here, all Plaintiff does is allege that unknown persons at Anavex and the FDA met on a number of occasions to discuss Rett Syndrome, and that the FDA "would have" disclosed the supposed endpoint "requirement" during one or more of those meetings. Opp. 19. Missing are allegations with dates, who was present, or what specifically was discussed. Mem. 18. In addition, the Opposition ignores Plaintiff's critical requirement to *specifically* identify the reports or statements from which Defendants learned facts contrary to the public representations. Mem. 19. Plaintiff has not done so here—the Amended Complaint does not cite a single document, meeting, or witness. See Mem. 17-19. Plaintiff thus fails to meet her burden. "Defendants do not bear the burden of disproving scienter, and [a plaintiff's] insinuations of foreknowledge fail to prove it." Koplyay v. Cirrus Logic, Inc., No. 13-cv-790, 2013 WL 6233908, *8 (S.D.N.Y. Dec. 2, 2013).

The Opposition tries to argue scienter through the disfavored "core operations" doctrine. As explained in the Memorandum (and unaddressed by Plaintiff), a general allegation about core operations is insufficient to plead the necessary inference of scienter absent allegations of fact from which one could infer that the matters were reported to defendants, such as internal witnesses or specific reports. Mem. 17-18 (citing cases); see also In re AT&T/DirecTV Now Sec. Litig., 480 F. Supp. 3d 507, 533 (S.D.N.Y. 2020) ("[C]ourts in this circuit have generally invoked the doctrine only to bolster other evidence of scienter, rather than relying on it as an independently sufficient basis."). Moreover, assertions about the importance of the Excellence trial or that Dr. Missling spoke about endpoints does nothing to address the central deficiency: Plaintiff has not alleged with the required specificity that the supposed FDA "requirement" existed and that anyone at Anavex knew about it. Even if "core operations" could support an inference that Dr. Missling would have

known details about the Excellence study, no particularized allegations support that Anavex was aware of any such FDA "requirement." As one of Plaintiff's own cases explains: "Of course, it is not enough to say that senior management would have paid some attention to the product that they were raving about; the complaint must allege particular facts strongly suggesting that that attention exposed them to information that either rendered their public statements false or necessarily invited further investigation." Constr. Indus. & Laborers Joint Pension Tr. v. Carbonite, Inc., 22 F.4th 1, 9–10 (1st Cir. 2021) (citing cases that failed to plead scienter, including where the plaintiff "failed to allege that *anyone* in the company was aware of facts contrary to the allegedly misleading public statements, so it could hardly present a strong inference that the senior officer defendants possessed such knowledge, regardless of the relevant product's import").[4]

Otherwise, the Opposition merely repeats various allegations without addressing any of Defendants' arguments. Compare Opp. 20-21 with Mem. 20-21 (concerning the timing of announcing results, Anavex announcing "off-topic" press releases, and Plaintiff's characterizations of statements made). The Opposition also does not respond at all regarding the allegation that Dr. Missling knew the Excellence results in August 2023. See Mem. 19. Accordingly, claims based on that allegation are properly considered conceded. See Francisco v. Abengoa, S.A., 481 F. Supp. 3d 179, 211 n.9 (S.D.N.Y. 2020).

Finally, despite a passing statement that motive and opportunity were sufficiently alleged (Opp. 19), the only statements in the Opposition remotely on this point repeat the general desire to maintain stock price and quote another case to argue that Defendants "benefited in a concrete

[4] Even if the core operations doctrine applied, "courts have required that the operation in question constitute nearly all of a company's business before finding scienter based on the 'core operations doctrine.'" Tyler v. Liz Claiborne, Inc., 814 F. Supp. 2d 323, 343 (S.D.N.Y. 2011). The Amended Complaint does not allege this. Indeed, Plaintiff acknowledges that Anavex's business is not so limited and that Anavex2-73 has potential uses for other diseases. Opp. 4; AC ¶ 17.

and personal way from the purported fraud," without explaining how. Such conclusory statements and generalized motives are insufficient. Mem. 16-17. Indeed, the allegations undermine any plausible motive: Plaintiff submits that Defendants knew that the FDA would not accept the RSBQ AUC endpoint, yet nevertheless proceeded to devote substantial resources toward two studies destined for failure. Absent concretely pled facts supporting her theory, the inference that Defendants would do this "while secretly believing that FDA approval was unlikely, impossible, or, if achievable, only on a delinquent time schedule—is implausible and conjectural." In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 531-32 (S.D.N.Y. 2015); see also Gillis, 197 F. Supp. 3d at 600.

**III. The Opposition Does Not Salvage the Loss Causation Deficiencies**

Regardless of the pleading standard, the allegations must still be plausible and support that a decline in stock price was "caused by the disclosure of the truth that Defendants had previously allegedly misrepresented." Biovail, 615 F. Supp. 2d at 229. "[L]oss causation cannot be alleged plausibly in so conclusory a fashion" as to simply assert that a stock drop was tied to fraud without pleading facts sufficient to support an inference that it was the alleged fraud and not some other factor that proximately caused the loss. In re New Energy Sys. Sec. Litig., 66 F. Supp. 3d 401, 406 (S.D.N.Y. 2014). Here, the market declines are divorced from the alleged fraud.

Plaintiff attempts to conflate various separate concepts in an effort to satisfy loss causation. Neither the February 7, 2023, nor the January 2, 2024, disclosures revealed anything about the allegedly hidden information: i.e., that the FDA required use of certain endpoints. Instead, they announced that Excellence would not use RSBQ AUC and announced the Excellence results. See Garber, 537 F. Supp. 2d at 617 (rejecting loss causation allegations based on statements that did not correctively disclose the alleged omissions). In fact, Plaintiff does not point to anything ever disclosing an FDA "requirement," even as of today. Mem. 24-25.

Plaintiff is incorrect that all that is required is that the broad "subject matter" of the alleged concealed information "relate[] in some part" to the corrective disclosure, and that therefore a press release about Excellence results satisfies loss causation for a fraud based on omitting an FDA endpoint requirement. Instead, as the Second Circuit has explained, "'a plaintiff must allege that the subject of the fraudulent statement or omission was the cause of the actual loss suffered,' i.e., that the misstatement or omission *concealed something from the market that, when disclosed*, negatively affected the value of the security." Lentell v. Merrill Lynch & Co., Inc., 396 F.3d 161, 173 (2d Cir. 2005) (citations omitted) (emphasis added). Plaintiff's alternative broad standard would eviscerate the loss causation requirement and would have led numerous cases to come out differently. E.g., Biovail, 615 F. Supp. 2d at 229 (finding plaintiff failed to allege loss causation premised on stock drop after the FDA declined to approve drug application, explaining that the complaint did not identify anything that publicly revealed the alleged misrepresentation that defendants believed the FDA would accept a particular type of study).

Plaintiff's primary case, Abramson v. NewLink Genetics Corp., 965 F.3d 165 (2d Cir. 2020), is easily distinguishable. The court there found that the release of bad study results constructively disclosed that earlier statements touting enrollment numbers were false because "a sufficient number of improper enrollments would naturally and predictably affect a trial's statistical integrity." Id. at 179-80. Here, by contrast, the allegedly undisclosed fact was that the FDA required particular endpoints. But Anavex disclosed to the market that it would be using certain endpoints partway through the Class Period. The later announcement of Excellence results did not constructively disclose a hidden FDA "requirement." Moreover, the Amended Complaint repeatedly alleges that the market doubted the acceptance of RSBQ AUC. AC ¶¶ 53-57, 60. Materialization of a *known* risk is not actionable. In re New Energy, 66 F. Supp. 3d at 406 & n.33.

Finally, Plaintiff's arguments about the market reaction on February 7, 2023, are inapposite and rely on authority that addresses reliance, not loss causation. See Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC, 310 F.R.D. 69, 96 (S.D.N.Y. 2015) (making clear that the two-day event study evidence was not being offered to support loss causation). The cases also confirm that a securities fraud class action must cut off the class period on the date a statement cures the market. Id. at 96-97. As Defendants explained, the stock price *increased* when the company announced Excellence would not use RSBQ AUC, which negates loss causation. Mem. 23-24; see Waters v. Gen. Elec. Co., No. 08-cv-8484, 2010 WL 3910303, at *8 (S.D.N.Y. Sept. 29, 2010) ("The Court cannot find, and Plaintiffs have not cited, a single section 10b-5 case in which the plaintiff prevailed on a motion to dismiss when the stock price increased after an announcement revealing an alleged fraud."), aff'd sub nom., GE Invs. v. Gen. Elec. Co., 447 F. App'x 229 (2d Cir. 2011).

**CONCLUSION**

For all of the reasons outlined above and in the Memorandum, the Court should dismiss the Amended Complaint with prejudice.[5]

[5] Plaintiff's request for leave to file another amended complaint should be denied. This is already a second bite at the apple. Having started this litigation with a clearly unsupported theory, Plaintiff pivoted to something entirely new in the Amended Complaint, which also fails for the reasons explained. It is not apparent how any further amendment could be successful. Cf. Biovail, 615 F. Supp. 2d at 233 ("Because plaintiff has already amended its complaint once, and because the flaws in pleading are incurable on the facts of this case, dismissal is with prejudice."); SRM Global Fund L.P. v. Countrywide Fin. Corp., No. 09-cv-5064, 2010 WL 2473595, *15 (S.D.N.Y. June 17, 2010) (denying leave to amend a second time, when the plaintiff "fail[ed] to identify with specificity those facts that would permit a second amended complaint to survive another motion to dismiss"); see also Kleinman v. Elan Corp., plc, 706 F.3d 145, 156-57 (2d Cir. 2013) (affirming district court decision not to grant leave to amend an already-amended complaint where the plaintiff's proposed new allegations were substantially the same as those rejected).

Date: September 20, 2024

Respectfully submitted,

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